



Patent Application
Docket No. UF-304XC2
Serial No. 10/691,002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : David M. Naff
Art Unit : 1651
Applicants : Laurie B. Gower, Matthew J. Olszta, Elliot P. Douglas,
Sivakumar Munisamy, Donna L. Wheeler
Serial No. : 10/691,002
Filed : October 22, 2003
For : Biomimetic Organic/Inorganic Composites, Processes for Their Production,
and Methods of Use

Commissioner for Patents
P.O. Box 1450
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DECLARATION OF LAURIE B. GOWER, PH.D., UNDER 37 C.F.R. §1.132

Sir:

I, Dr. Laurie B. Gower, hereby declare:

THAT, I am an associate professor within the Department of Materials Science and Engineering at the University of Florida;

THAT, I am a co-inventor of the technology described and claimed in patent application Serial No. 10/691,002 (hereinafter the '002 application);

THAT, I have read and understood the specification and claims of the '002 application and the Office Action dated July 20, 2006;

THAT, I am a co-author on the following presentations:

- I. Olszta, M. and Gower, L., "Biomimetic mineralization of type-I collagen", presented at the Seventh International Conference on the Chemistry and Biology of Mineralized Tissues, November 4-9, 2001, Sawgrass, Florida (referred to in the Office Action and herein as the Olszta R9 presentation);
- II. Olszta, M., "Biomimetic mineralization of type-I collagen" presented at UEF Biomimetic Engineering Conference, March 3-7, 2002, Destin, FL

(referred to in the Office Action and herein as the Olszta R11 presentation); and

- III. Olszta, M. and Gower, L., "Biomimetic Mineralization of Collagen for Nanostructured Composites", presented at the Gordon Research Conference, June 2001 (referred to in the Office Action and herein as the Olszta R27 presentation);

AND, being thus duly qualified, do further declare:

1. Claims 1-5, 7, 8, 11-13, 15, 24-29, and 31 in the '002 application have been rejected under 35 U.S.C. 102(b) in the Office Action on the ground that the claimed invention is anticipated by the above-referenced Olszta R9 presentation, Olszta R11 presentation, or Olszta R27 presentation. In addition, claims 6, 16, 17, and 18 have been rejected under 35 U.S.C. §103(a) on the ground that the claimed invention is obvious over the Olszta R9 presentation, Olszta R11 presentation, or Olszta R27 presentation, or in view of the Silver *et al.* patent (U.S. Patent No. 5,532,217). Claims 9, 10, and 14 have been rejected under 35 U.S.C. §103(a) on the ground that the claimed invention is obvious over the Olszta R9 presentation, Olszta R11 presentation, or Olszta R27 presentation, or in view of the Rhee *et al.* patent (U.S. Patent No. 5,800,541). Claims 19-21 and 23 have been rejected under 35 U.S.C. §103(a) on the ground that the claimed invention is obvious over the Olszta R9 presentation, Olszta R11 presentation, or Olszta R27 presentation, or in view of the Liu patent (U.S. Patent No. 6,300,315). Claim 22 has been rejected under 35 U.S.C. §103(a) on the ground that the claimed invention is obvious over the Olszta R9 presentation, Olszta R11 presentation, or Olszta R27 presentation, or in view of the Liu patent in view of the Rhee *et al.* patent. Claim 30 has been rejected under 35 U.S.C. §103(a) on the ground that the claimed invention is obvious over the Olszta R9 presentation, Olszta R11 presentation, or Olszta R27 presentation, or in view of the Brown *et al.* patent (U.S. Patent No. 6,201,039). Claims 32, 33, 35, and 36 have been rejected under 35 U.S.C. §103(a) on the ground that the claimed invention is obvious over the Olszta R9 presentation, Olszta R11 presentation, or Olszta R27 presentation, or in view of the Connelly *et al.* patent (U.S. Patent No. 6,995,013). Claims 34 and 37-39 have been rejected under 35 U.S.C. §103(a) on the ground that the claimed invention is obvious over the Olszta R9 presentation, Olszta R11 presentation, or Olszta

R27 presentation, or in view of the Song *et al.* patent (U.S. Patent No. 5,418,222). Dr. Matthew J. Olszta and I are the authors of the Olszta R9, Olszta R11, and Olszta R27 presentations and are co-inventors on the '002 application. The inventorship of the claimed invention and the authorship of the Olszta R9, Olszta R11, and Olszta R27 presentations differ in that although Drs. Elliot P. Douglas, Sivakumar Munisamy, and Donna L. Wheeler are co-inventors on the '002 application, they are not co-authors of the Olszta R9, Olszta R11, and Olszta R27 presentations.

2. As discussed in more detail below, although Drs. Douglas, Munisamy, and Wheeler contributed to the conception of various aspects of the claimed invention, they were not included as co-authors of the Olszta R9, Olszta R11, and Olszta R27 presentations because they did not participate in the presentations and were not directly involved in the experiments described in the presentations.

3. Drs. Douglas and Wheeler contributed to the conception of the claimed invention. However, Drs. Douglas and Wheeler were not directly involved in the experiments that were subsequently carried out in my laboratory by me and Dr. Olszta, a graduate student in my laboratory at the time. The Olszta R9, Olszta R11, and Olszta R27 presentations describe these later experiments. For this reason, Dr. Olszta and I were the only authors on the Olszta R9, Olszta R11, and Olszta R27 presentations, even though Drs. Douglas and Wheeler are co-inventors on the '002 application because they contributed to the conception of the process for making organic/inorganic composites of the invention, how it would be developed, and how the resultant organic/inorganic composites would be characterized.

4. Dr. Douglas, Dr. Olszta, and I contributed to the conception of mineralizing a collagen matrix using the process of the invention. The experiments described in the Olszta R9, Olszta R11, and Olszta R27 presentations, which were actually carried out by Dr. Olszta and myself, confirmed that the process conceived by Dr. Douglas, Dr. Olszta, and myself worked for its intended purpose. Dr. Douglas did not participate in the presentations and was not directly involved in carrying out the

experiments described in the presentations; however, it is only for these reasons that he was not included as a co-author of the Olszta R9, Olszta R11, and Olszta R27 presentations.

5. Dr. Wheeler contributed to that aspect of the invention involving the incorporation of proteins, such as growth factors, to the composite of the invention (e.g., claims 20, 32, and 33). This aspect of the invention is not described in the Olszta R9 and Olszta R27 presentations.

6. Dr. Munisamy joined my laboratory as a post-doctoral associate, and was included as an inventor on the '002 application because he contributed to the conception of an aspect of the claimed invention during his work on the project. Dr. Munisamy demonstrated that a collagen matrix could be mineralized by the process of the invention, using a calcium phosphate precursor phase, which was formed by combining calcium chloride and a combination of polymers to form an aqueous solution, and reacting the aqueous solution with ammonium phosphate vapor. This procedure is not described in the Olszta R9, Olszta R11, and Olszta R27 presentations.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or of any patent issuing thereon.

Further declarant sayeth naught.

Signed:

Laurie B. Gower
Laurie B. Gower, Ph.D.

Date:

12-15-2006